

REMARKS

Claims 1-20, 28 and 44 are pending in the present application. Claims 1 and 44 are amended.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. November 21, 2005 Notice of Non-Compliance

This is submitted in response to the November 21, 2005 Notice of Non-Compliance whereby Applicants' August 1, 2005 response to the February 1, 2005 Office Action was rejected for failure to comply with the amendment format required by 37 C.F.R. 1.121 because the text of withdrawn claim 28 was not included in the amended claim listing. Applicants' present response both corrects this omission and once again submits Applicants' previously submitted amendments to claims 1 and 44.

II. The Rejection of Claims 1-20 under 35 U.S.C. 112

In the February 1, 2005 Office Action, claims 1-20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner alleged that the step of "predicting the amount of fluorescent marker" requires forecasting into the future.

This rejection is respectfully traversed. The specification discloses that the process of the predicting the amount of fluorescent marker is a routine task to the skilled artisan carried out using readily available equipment (computers and computer software). The specification also discloses specifically how the prediction can be made, e.g., by comparing the light emitted from the granular composition being analyzed to the light emission pattern from a granular composition of known properties. In this regard, the Examiner is directed to the specification at page 9 to page 10, under the heading "Processing of detected signal." This section of the specification discloses:

Conversion of the emitted light, in the detector, into an electronic signal and converting this signal into a measure, such as a number, from which a prediction of the amount of emitted light and the amount of fluorescent marker accessible to excitation may be inferred, is known to the skilled person, as analysers for making fluorescence analysis are abundantly available. The prediction may suitably be made by comparing the amount of the emitted light from an unknown granular composition with data on emitted light from a granular composition of known properties, and thus predicting in the unknown granular composition the amount of fluorescent marker accessible to excitation. The output of most detectors

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such as photo multiplication based types or some photo diode based types is an analogue signal. Most detectors such as many cameras, which comprise numerous single photo diode detectors, may have a build in analogue-digital converter capable of converting the analogue signal into a digital signal, which is more suitable for computerized data processing. Depending on the fluorescent marker and property of the granular composition one wishes to link to the amount of emitted light, the digital data arising from the emitted light may be subjected to processing. This processing is suitably performed in a computer system using software designed for such processes. Such software may be the LabView software as used in the examples herein or any other software providing the necessary capabilities for performing the desired data processing to link the amount of emitted light to a property of the granular composition. The data processing may include operations such as particle counting, gauging, pattern matching (grey scale and colour), statistics, thresholds, multivariate image analysis, AMT, blob analysis, area calculation, edge detection, morphology analysis, convolution, folding and unfolding, FFT, various filtering techniques e.g. median filtering - all techniques known to the skilled analyst, which are data processing functions included in commercially available software. In the process of transferring data to a computing unit the computing unit usually have to be equipped with hardware capable of acquiring the data from the detector for storage in the computing unit. Such hardware, e.g. data acquisition cards, is well known. When using a CCD or other type of camera producing 2 dimensional images of fluorescent granules it is also advantageous to use, in the computing unit, software capable of recording the 2 dimensional images in form of discrete digital still images. Such software is known as frame grabber programs. The speed at which such software is capable of recording images usually depends on the speed of the computing unit, and of for most fluorescence analysis purposes a speed of about 15 frames per second suffices. This means that 15 two-dimensional images are recorded per second. (emphasis added).

As described above, the skilled artisan would plainly understand that prediction of the amount of fluorescent marker entails converting the signal into a measure, such as a number, from which a prediction of the amount of emitted light can be made. The skilled artisan would also plainly understand that there are many well known computer programs for carrying out this process. The skilled artisan would also readily understand that a prediction can be made by comparing the measure to a standard. Thus, the Examiner's assertion that the process of correlating the amount of fluorescent marker in the granular composition with the amount of emitted light (and predicting the amount of fluorescent marker) involves some indefinite forecasting into the future is simply not valid as the skilled artisan would clearly understand what this process entails, and the specification specifically discloses how to carry out such prediction.

Moreover, the claims have now been amended to further clarify that the correlation/prediction is performed by comparing the emitted light to a standard (i.e., light emitted from the granular composition with light emitted light from a granular composition of known properties). Prediction by comparing to a sample to a standard is clearly a routine process that is involved in almost every scientific analysis, including the claimed analysis, and is not an indefinite process.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claim 44 under 35 U.S.C. 103

Claim 44 remains rejected under 35 U.S.C. 103(a) as unpatentable over McNamara et al. The Office states that McNamara et al. (Figures 4A, 4B, 5A and 5B, etc.) show granular cellular samples, which are granular compositions as recited in the instant claims. This rejection is respectfully traversed.

McNamara et al.'s granular samples are not "granular compositions" as recited by the instant claims. McNamara et al. is directed to methods for *in situ* cellular analysis. Figures 4A, 4B, 5A and 5B, thus, show stains of cells and chromosomes. Cells and chromosomes are not, however, granular compositions. Rather, the granular compositions of the present invention are compositions used for delivering active ingredients, such as, enzymes. See the specification at page 10, line 29 to page 15, lines 17, discussing the properties and preparation of granules. Thus, McNamara et al. does not teach analysis of "granular compositions" of the claimed invention, and there is no motivation to apply the McNamara et al. cellular analysis process to the analysis of granular composition as recited in the claimed invention.

In the last office action, the Examiner cites the Specification's definition of granular composition, and concludes that the compositions of McNamara et al. have these properties. Applicants respectfully submit that term granular composition would not be interpreted to encompass the cells and chromosomes of McNamara et al. Claim 44 has been further amended, however, to clearly distinguish McNamara et al. by reciting a purified enzyme.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



Date: December 1, 2005

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